IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ANACOR PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 18-202-IMK
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF ANACOR'S MOTION TO STAY CASE

Plaintiff Anacor Pharmaceuticals, Inc. ("Anacor") hereby moves to stay this case until the Patent Trial and Appeal Board ("PTAB") issues final written decisions in *inter partes* review ("IPR") Nos. 2018-00168, 2018-00169, 2018-00170, and 2018-00171. If the PTAB finds that all of the claims of the patents are unpatentable, Anacor further moves to continue the stay until the time for appeal of the PTAB's decisions has expired or any appeals have terminated. In the alternative, Anacor respectfully requests that the Court enter a stay until Anacor's motion to transfer this case to the District of Delaware, currently pending before the Judicial Panel on Multidistrict Litigation ("JPML"), has been decided.

BACKGROUND

A. The *Inter Partes* Review Petitions Filed by Mylan and FlatWing.

In November 2017, FlatWing Pharmaceuticals, LLC ("FlatWing") petitioned the PTAB for *inter partes* review of all of the claims of U.S. Patent Nos. 9,459,938 ("the '938 patent"), 9,566,289 ("the '289 patent"), 9,566,290 ("the '290 patent"), and 9,572,823 ("the '823 patent")—the same four patents that are at issue in this case. FlatWing's petitions alleged that those patents (collectively, "the patents-in-suit") are unpatentable as obvious over the prior art.

See 35 U.S.C. § 103. In July 2018, Mylan Pharmaceuticals, Inc., filed petitions with the PTAB seeking to invalidate the same patents on identical grounds. The PTAB instituted trial on FlatWing's and Mylan's petitions and has consolidated them into the following four IPRs: IPR No. 2018-00168; IPR No. 2018-00169; IPR No. 2018-00170; and IPR No. 2018-00171.

The IPRs are at an advanced stage. Oral argument is scheduled to take place on March 1, 2019, and the PTAB is expected to issue its final written decisions in June 2019.

B. The Kerydin® ANDA Civil Actions Filed by Anacor.

Between September 5 and September 18, 2018—after the PTAB had already instituted trial on all of the patents-in-suit—Anacor received notice letters informing it that, in total, fourteen Abbreviated New Drug Applications ("ANDAs") have been filed with the FDA seeking approval to manufacture and sell generic versions of Anacor's Kerydin® (TAVABOROLE) TOPICAL SOLUTION, 5% ("Kerydin"), prior to the expiration of the patents-in-suit. Anacor's receipt of these notice letters triggered its forty-five day period to sue for infringement of the patents-in-suit under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(B)(III).

In response to these notice letters, Anacor filed four patent infringement actions in October 2018. Three of the four actions were filed in the United States District Court for the District of Delaware.[1] In total, Anacor sued twenty-two defendants—including Mylan

[1] The Delaware actions are captioned as follows: *Anacor Pharm., Inc. v. Lupin Ltd., Lupin Pharm., Inc., Encube Ethicals Pvt. Ltd., Glasshouse Pharm. Ltd. Canada, & FlatWing Pharma., LLC*, No. 1:18-cv-001606-RGA (D. Del.); *Anacor Pharm., Inc. v. Ascent Pharm., Inc., Zydus Pharm. (USA) Inc., Cadila Healthcare Ltd., Apotex Inc., Apotex Corp., Amneal Pharm. LLC, Perrigo Pharma Int'l DAC, Perrigo Co. plc, Aleor Dermaceuticals Ltd., Cipla Ltd., Cipla USA, Inc., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Taro Pharm. U.S.A., Inc., & Taro Pharm. Indus., Ltd.*, No. 1:18-cv-001673-RGA (D. Del.); and *Anacor Pharm., Inc. v. Mylan Pharm. Inc. & Mylan Inc.*, No. 1:18-cv-01699-RGA (D. Del.).

Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan")—in Delaware.[2] However, because Mylan objected to venue in the District of Delaware, Anacor also filed a fourth, substantively identical lawsuit against Mylan in this district (the present action).

The three Delaware cases are currently pending before Judge Richard G. Andrews, and are at essentially the same procedural stage as this case: most defendants have responded to Anacor's complaints, but no conferences have been held, no discovery has taken place, and no schedules have been set.[3] On November 26, 2018, FlatWing moved to stay the Delaware case in which it is a defendant until the PTAB issues a final written decision in the pending IPRs. *See Anacor Pharm., Inc. v. Lupin Ltd., et al.*, No. 18-cv-1606-RGA, D.I. 23–25 (D. Del. Nov. 26, 2018). In response, on December 10, 2018, Anacor filed a cross-motion to stay all three Delaware cases until the PTAB issues final written decisions in the pending IPRs and, if the PTAB finds that all of the claims of all of the patents-in-suit are unpatentable, until the time for appeal of the PTAB's decisions has expired or any appeals have terminated. *See id.*, D.I. 34 (D. Del. Dec. 10, 2018); *Anacor Pharm., Inc. v. Ascent Pharm., Inc.*, No. 18-1673-RGA, D.I. 46 (D. Del. Dec. 10, 2018); *Anacor Pharm., Inc. v. Mylan Pharm. Inc.*, No. 18-1699-RGA, D.I. 10 (D. Del. Dec. 10, 2018). Both FlatWing's motion and Anacor's cross-motion remain pending.

Separately, on January 7, 2019, Anacor filed a motion with the JPML seeking to transfer this case to Judge Andrews in the District of Delaware for coordinated and consolidated pretrial proceedings with the cases already pending in that district. *See In re: Kerydin (Tavaborole*

[2] There is no dispute that the twenty non-Mylan defendants are subject to jurisdiction and venue in the District of Delaware.

[3] Mylan has moved to dismiss Anacor's Delaware complaint on the basis of allegedly improper venue, but the parties have not yet completed briefing on that motion.

Topical Solution 5% Patent Litig., MDL No. 2884, D.I. 1 (J.P.M.L. Jan. 7, 2019). Anacor's transfer motion is currently pending.

On January 9, 2019, Mylan filed in Delaware a response to FlatWing's stay motion and Anacor's cross-motion, stating that "[a] stay of [the Delaware] litigation is appropriate so long as the stay: (i) expires upon issuance of the IPR final written decisions[;] (ii) does not serve as a basis for extension of the regulatory stay of approval of [Mylan Pharmaceuticals Inc.]'s ANDA product; and (iii) does not delay resolution of" Mylan's motion to dismiss the Delaware case. *Anacor Pharm., Inc. v. Mylan Pharm. Inc.*, No. 18-1699-RGA, D.I. 22 (D. Del. Jan. 9, 2019). Counsel for Mylan has represented that Mylan's position on the present motion is the same one it articulated in its Delaware response.

Mylan's second and third conditions are met here, as Anacor has agreed not to argue that a stay should serve as the basis for an extension of the regulatory stay of approval of Mylan's ANDA Product, and unlike in Delaware, Mylan has not moved to dismiss the present action. But Mylan and Anacor disagree as to the appropriate length of the proposed stay if the PTAB determines that all of the claims of the patents are unpatentable. Mylan proposes that the stay terminate after the IPRs conclude, regardless of the result. Anacor proposes that the stay terminate upon either confirmation of the patentability of at least one of the claims at issue in the IPRs, or, if all claims are determined by the PTAB to be unpatentable, after conclusion of any appeal or the expiration of time to appeal (if no appeal is taken).

ARGUMENT

I. This Court Should Stay this Case and Await Decisions in the Pending IPRs.

Courts, including district courts in this circuit, typically consider three factors when deciding whether to stay a case pending PTAB review of a patent-in-suit: (1) whether a stay will simplify the issues in question and trial of the case; (2) whether discovery is complete and

whether a trial date has been set; and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the nonmoving party. *E.g.*, *Cobalt Boats, LLC v. Sea Ray Boats, Inc.*, No. 2:15cv21, 2015 WL 7272199, at *2 (E.D. Va. Nov. 16, 2015); *Univ. of Va. Patent Found. v. Hamilton Co.*, No. 3:13-cv-00033, 2014 WL 4792941, at *2 (W.D. Va. Sept. 25, 2014); *Softview LLC v. Apple Inc.*, Nos. 12-989-LPS & 10-389-LPS, 2013 WL 4757831, at *1 (D. Del. Sept. 4, 2013). District courts applying these factors routinely issue stays pending the outcome of IPR proceedings before the PTAB. *See, e.g.*, *Cobalt Boats*, 2015 WL 7272199; *Univ. of Va. Patent Found.*, 2014 WL 4792941; *Softview*, 2013 WL 4757831. All of the above factors weigh in favor of staying this case.

A. Anacor's Proposed Stay Will Simplify the Issues and Trial of the Case.

There is no reasonable dispute that the PTAB's decisions in the pending IPRs will simplify the issues in question and trial of the case. Mylan has petitioned the PTAB to review—and the PTAB has agreed to review—the patentability of all of the claims of the patents-in-suit on the ground that "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Under these circumstances, the PTAB's decisions will substantially narrow the issues in dispute for at least two reasons.

First, the PTAB's decisions will estop Mylan from relitigating in this proceeding the obviousness of any claims that survive the PTAB's review. *See* 35 U.S.C. § 315(e)(2) ("The petitioner in an inter partes review . . . may not assert . . . in a civil action arising in whole or in part under section 1338 of title 28 . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review."). In its notice letter informing Anacor that it had submitted an ANDA seeking FDA approval to manufacture and sell a generic version of Kerydin®, Mylan asserted principally that the patents-in-suit are invalid as

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